

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

PATSY BARKER, KATHERINE WELLS,
KENNETH SMITH, and DANNY
BARKER,

Plaintiffs,

vs.

JOHNSON & JOHNSON, DEPUY
ORTHOPAEDICS, INC., and A1A, INC.,

Defendants.

Case No. 2:13-cv-1930

DEFENDANTS JOHNSON &
JOHNSON AND DEPUY
ORTHOPAEDICS, INC.'S ANSWER
AND DEFENSES TO PLAINTIFFS'
COMPLAINT

Defendants Johnson & Johnson and DePuy Orthopaedics, Inc. (collectively "Defendants") hereby respond to Plaintiffs' Complaint as follows. Pursuant to Rule 8(b)(1) of the Federal Rules of Civil Procedure, for each paragraph in which Plaintiffs assert allegations against individuals or entities other than Johnson & Johnson and DePuy Orthopaedics, Inc., Defendants neither admit nor deny those allegations.

I. PARTIES AND JURISDICTION

1. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 1 and therefore deny them.

1 2. Defendants lack knowledge or information sufficient to form a belief as to the
2 truth of the allegations contained in Paragraph 2 and therefore deny them.

3 3. Defendants lack knowledge or information sufficient to form a belief as to the
4 truth of the allegations contained in Paragraph 3 and therefore deny them.

5 4. Defendants lack knowledge or information sufficient to form a belief as to the
6 truth of the allegations contained in Paragraph 4 and therefore deny them.

7 5. Defendants admit that Johnson & Johnson is a New Jersey corporation with its
8 principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey
9 08933. Defendants deny the remaining allegations contained in Paragraph 5.

10 6. Defendants admit that DePuy Orthopaedics, Inc. is an Indiana Corporation
11 with its principal place of business at 700 Orthopaedic Drive, Warsaw Indiana 46582 and that
12 its products are prescribed, sold, and used in the State of Washington. Defendants deny the
13 remaining allegations contained in Paragraph 6 as phrased.

14 7. Defendants admit that A1A, Inc. is a Washington corporation with its principal
15 place of business at 12646 Interurban Avenue, Seattle, WA 98168. Defendants lack
16 knowledge or information sufficient to form a belief as to the truth of the remaining
17 allegations contained in Paragraph 7 and therefore deny them.

18 8. As to the allegations contained in Paragraph 8, Defendants deny that venue and
19 jurisdiction are proper.

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22 **II. STATEMENT OF FACTS**

23 9. Defendants admit that DePuy Orthopaedics, Inc. is the responsible U.S. entity
24 for the design, manufacture, label, distribution, marketing, and sale of the ASR™ XL System
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1 and the ASR™ Surface Replacement femoral head component. Defendants deny the
2 remaining allegations contained in Paragraph 9.

3 10. Defendants lack knowledge or information sufficient to form a belief as to the
4 truth of the allegations contained in Paragraph 10 and therefore deny them.

5 11. Defendants deny the allegations contained in Paragraph 11.

6 12. Defendants admit that A1A, Inc. delivered ASR™ devices in the State of
7 Washington beginning in December 2008. Defendants deny the remaining allegations
8 contained in Paragraph 12 and expressly deny that A1A is a seller of ASR™ devices.
9

10 13. Defendants admit that on August 24, 2010, DePuy Orthopaedics, Inc. issued a
11 voluntary, global recall of the ASR™ XL System and the ASR™ Hip Resurfacing System.
12 Defendants deny the remaining allegations contained in Paragraph 13 as phrased.

13 14. Defendants lack knowledge or information sufficient to form a belief as to the
14 truth of the allegations contained in Paragraph 14 and therefore deny them.

15 15. Defendants lack knowledge or information sufficient to form a belief as to
16 Plaintiff's alleged medical condition, diagnosis, prognosis or treatment and therefore deny
17 those allegations. Defendants deny the remaining allegations contained in Paragraph 15.
18

19 16. Defendants deny the allegations contained in Paragraph 16.

20 17. Defendants deny the allegations contained in Paragraph 17.

21 18. No corresponding paragraph exists in Plaintiff's Complaint and therefore no
22 response is necessary.
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III. CAUSES OF ACTION

Products Liability

19. Defendants admit that DePuy Orthopaedics, Inc. is the responsible U.S. entity for the design, manufacture, label, distribution, marketing, and sale of the ASR™ XL System and the ASR™ Surface Replacement femoral head component. Defendants deny the remaining allegations contained in Paragraph 19.

20. Paragraph 20 contains legal statements and conclusions to which no response is required. To the extent that a response is required, Defendants deny that Paragraph 20 is an accurate and complete statement of the applicable law. Further answering, Defendants deny that Johnson & Johnson is a seller of ASR™ devices. Defendants deny the remaining allegations contained in Paragraph 20.

21. Paragraph 21 contains legal statements and conclusions to which no response is required. To the extent that a response is required, Defendants deny that Paragraph 21 is an accurate and complete statement of the applicable law. Further answering, Defendants deny that A1A, Inc. is a seller of ASR™ devices and deny the remaining allegations contained in Paragraph 21.

22. Defendants admit that DePuy Orthopaedics, Inc. is the responsible U.S. entity for the design, manufacture, label, distribution, marketing, and sale of the ASR™ XL System and the ASR™ Surface Replacement femoral head component. Defendants deny the remaining allegations contained in Paragraph 22 and expressly deny that the ASR™ devices are “unreasonably dangerous” or “defective.”

23. Defendants admit that DePuy Orthopaedics, Inc. is the responsible U.S. entity for the design, manufacture, label, distribution, marketing, and sale of the ASR™ XL System

1 and the ASR™ Surface Replacement femoral head component. Defendants deny the
2 remaining allegations contained in Paragraph 23 and expressly deny that the ASR™ devices
3 are “unreasonably dangerous” or “defective.”

4 24. Defendants deny the allegations contained in Paragraph 24.

5 25. Defendants deny the allegations contained in Paragraph 25.

6 26. Defendants deny the allegations contained in Paragraph 26 and expressly deny
7 that the ASR™ devices are “not reasonably safe.”
8

9 27. Defendants deny the allegations contained in Paragraph 27 and expressly deny
10 that the ASR™ devices are “not reasonably safe.”

11 ***Consumer Protection Act***

12 28. Defendants re-allege their answers to all paragraphs as if fully set forth herein.

13 29. Defendants deny the allegations contained in Paragraph 29 and expressly deny
14 that it made misrepresentations.

15 30. Defendants deny the allegations contained in Paragraph 30 and expressly deny
16 that they “engaged in unfair and deceptive actions.”
17

18 31. Defendants deny the allegations contained in Paragraph 31.

19 32. Defendants deny the allegations contained in Paragraph 32.

20 33. Defendants deny the allegations contained in Paragraph 33 and expressly deny
21 that Plaintiff is entitled to relief of any kind.

22 ***Breach of Implied Warranty***

23 34. Defendants re-allege their answers to all paragraphs as if fully set forth herein.

24 35. Defendants admit that DePuy Orthopaedics, Inc. is the responsible U.S. entity
25
26 for the design, manufacture, label, distribution, marketing, and sale of the ASR™ XL System.

1 Further answering, Defendants state that DePuy Orthopaedics, Inc.'s written communications
2 about its products speak for themselves. Defendants deny the remaining allegations contained
3 in Paragraph 35.

4 36. Defendants deny the allegations contained in Paragraph 36.

5 37. Defendants deny the allegations contained in Paragraph 37.

6 ***Breach of Implied Warranty of Merchantability***

7 38. Defendants re-allege their answers to all paragraphs as if fully set forth herein.

8 39. Defendants deny the allegations contained in Paragraph 39.

9 40. Defendants deny the allegations contained in Paragraph 40.

10 41. Defendants deny the allegations contained in Paragraph 41.

11 42. Defendants deny the allegations contained in Paragraph 42.

12 ***Implied Warranty of Fitness for a Particular Purpose***

13 43. Defendants re-allege their answers to all paragraphs as if fully set forth herein.

14 44. Defendants lack knowledge or information sufficient to form a belief as to
15 what Plaintiff or her orthopedic surgeon relied upon at any time, whether Plaintiff purchased
16 an ASR™ device or whether an ASR™ device was implanted in the Plaintiff and therefore
17 deny those allegations. Defendants deny the remaining allegations contained in Paragraph 44.

18 45. Defendants deny the allegations contained in Paragraph 45.

19 46. Defendants deny the allegations contained in Paragraph 46.

20 47. Defendants deny the allegations contained in Paragraph 47.

21 ***Outrage***

22 48. Defendants re-allege their answers to all paragraphs as if fully set forth herein.

23 49. Defendants deny the allegations contained in Paragraph 49.

1 50. Defendants deny the allegations contained in Paragraph 50.

2 51. Defendants deny the allegations contained in Paragraph 51.

3 52. Defendants deny the allegations contained in Paragraph 52.

4 ***Negligent Infliction of Emotional Distress***

5 53. Defendants re-allege their answers to all paragraphs as if fully set forth herein.

6 54. The allegations contained in Paragraph 54 contain legal statements or
7 conclusions of law to which no response is required. To the extent a response is required, the
8 allegations are denied.
9

10 55. Defendants deny the allegations contained in Paragraph 55.

11 56. Defendants deny the allegations contained in Paragraph 56.

12 57. Defendants deny the allegations contained in Paragraph 57.

13 **IV. NOTICE**

14 58. Paragraph 58 contains legal statements and conclusions to which no response
15 is required. To the extent that a response is required, Defendants deny that Paragraph 58 is an
16 accurate and complete statement of the applicable law.
17

18 **IV. DAMAGES**

19 59. Defendants deny the allegations contained in Paragraph 59 and expressly deny
20 that Plaintiff is entitled to relief of any kind.

21 60. Defendants admit that Plaintiff claims damages set forth in Paragraph 60 but
22 expressly denies that Plaintiff is entitled to relief of any kind.
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24 61. Defendants deny the allegations contained in Paragraph 61 expressly deny that
25 Plaintiff is entitled to relief of any kind.
26

1 62. Defendants deny the allegations contained in Paragraph 62 expressly deny that
2 Plaintiff is entitled to relief of any kind.

3 63. Defendants deny the allegations contained in Paragraph 63 expressly deny that
4 Plaintiff is entitled to relief of any kind.

5 64. Defendants deny the allegations contained in Paragraph 64 expressly deny that
6 Plaintiff is entitled to relief of any kind.

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8 **V. PUNITIVE DAMAGES**

9 65. Defendants deny the allegations contained in Paragraph 65.

10 **VI. PRAYER FOR RELIEF**

11 66. As to the unnumbered “Prayer For Relief” following Paragraph 65 including
12 subparts (a) through (e), Defendants expressly deny that Plaintiffs are entitled to relief of any
13 kind.

14 **AFFIRMATIVE DEFENSES**

15 **FIRST AFFIRMATIVE DEFENSE**

16
17 Plaintiffs knowingly and voluntarily assumed any and all risks associated with the use
18 of the products at issue in this case, and such assumption of the risks bar in whole or in part
19 the damages Plaintiffs seek to recover herein.

20 **SECOND AFFIRMATIVE DEFENSE**

21 At all times mentioned herein, Plaintiffs were negligent, careless, and at fault, and
22 conducted themselves so as to contribute substantially to Plaintiffs’ alleged injuries and
23 damages. Said negligence, carelessness, and fault of Plaintiffs bar in whole or in part the
24 damages which Plaintiffs seek to recover herein.
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THIRD AFFIRMATIVE DEFENSE

Plaintiffs' alleged injuries and damages attributable to the use of the products at issue in this case, if any, were not legally caused by the products at issue, but instead were legally caused by intervening and superseding causes or circumstances.

FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' alleged damages, if any, are barred in whole or in part by Plaintiffs' failure to mitigate such damages.

FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred by the applicable statutes of limitation, statutes of repose, and doctrine of laches.

SIXTH AFFIRMATIVE DEFENSE

Defendants did not make to Plaintiffs, nor did they breach, any express or implied warranties and/or breach any warranties created by law. To the extent that Plaintiffs rely on any theory of breach of warranty, such claims are barred by applicable law, and for lack of privity with Defendants and/or for failure of Plaintiffs, or Plaintiffs' representatives, to give timely notice to Defendants of any alleged breach of warranty. Defendants further specifically pleads as to any breach of warranty claim all affirmative defenses under the Uniform Commercial Code existing and which may arise in the future as enacted in the State of Washington and any other state whose law is deemed to apply in this case.

SEVENTH AFFIRMATIVE DEFENSE

At the time of sale or delivery, the products conformed to the state-of-the-art for such products at that time.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' claims should be diminished in whole or in part in the amount paid to Plaintiffs by any party or non-party with whom Plaintiffs have settled or may settle.

NINTH AFFIRMATIVE DEFENSE

Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

TENTH AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred by the learned intermediary doctrine.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred by the doctrines of informed consent, release, and waiver.

TWELFTH AFFIRMATIVE DEFENSE

The injuries and damages claimed by Plaintiffs, if any, were caused in whole or in part by the acts or omissions of persons over whom Defendants have no control or right of control.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred by the equitable doctrine of estoppel.

FOURTEENTH AFFIRMATIVE DEFENSE

Upon information and belief, if the injuries referred to in the Complaint were caused by the products at issue, which is denied, the injuries are the result of an idiosyncratic reaction to the product.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' alleged injuries are a result of a pre-existing and/or unrelated medical condition for which Defendants are not responsible.

SIXTEENTH AFFIRMATIVE DEFENSE

To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001).

SEVENTEENTH AFFIRMATIVE DEFENSE

If the products at issue are unsafe in any way, they are unavoidably unsafe. Plaintiffs' purported actions are, therefore, barred by Comment k of § 402A of the Restatement (Second) of Torts and/or other applicable law.

EIGHTEENTH AFFIRMATIVE DEFENSE

Defendants are entitled to, and claim the benefits of, all defenses and presumptions set forth in or arising from any rule of law or statute in the state of Washington, Plaintiffs' alleged state of citizenship and residence, and any other state whose law is deemed to apply in this case. Defendants reserve the right to assert any additional defenses which may be disclosed during the course of additional investigation and discovery.

NINETEENTH AFFIRMATIVE DEFENSE

The claims of Plaintiffs should be dismissed, reduced, offset, or barred in accordance with the principles of comparative negligence and the New Jersey Joint Tortfeasors Law, N.J.S.A. §§ 2A:53A-3, *et seq.*

TWENTIETH AFFIRMATIVE DEFENSE

Defendants assert all defenses available under the Washington Consumer Protection Act, RCW §19.86.010, *et seq.*, or any other state's consumer protection and/or deceptive trade practices act deemed to apply to this case.

TWENTY-FIRST AFFIRMATIVE DEFENSE

If more than one entity, as that term is used in RCW §4.22.070, is found to be a fault, then fault should be apportioned among all at-fault entities, whether this includes Defendants, or not, and among all persons or entities that have settled with Plaintiffs at the time of trial. Defendants hereby request apportionment pursuant to RCW §4.22 *et seq.*

TWENTY-SECOND AFFIRMATIVE DEFENSE

Any claim for punitive or exemplary damages against Defendants is unconstitutional in that recovery of punitive or exemplary damages in this case would violate Defendants' constitutional rights to due process and equal protection under the Fourteenth Amendment to the Constitution of the United States and similar protections afforded by the Washington, New Jersey, and Indiana state constitutions, and any other state whose law is deemed to apply in this case, and that any law of the states of Washington, New Jersey, or Indiana, whether enacted by that state's legislature or founded upon a decision or decisions of the courts, or that of any other state whose law is deemed to apply in this case, that would permit recovery of punitive or exemplary damages, is unconstitutional under these provisions.

TWENTY-THIRD AFFIRMATIVE DEFENSE

Any claim for punitive or exemplary damages against Defendants is unconstitutional in that the standards for granting and asserting punitive or exemplary damages do not prohibit other plaintiffs from seeking and recovering such damages against Defendants for the same allegations of defect in the same products, and as such constitute multiple punishments for the same alleged conduct resulting in deprivation of Defendants' property without due process of law and will result in unjustified windfalls for Plaintiffs and Plaintiffs' counsel, in violation of the Sixth, Eighth, and Fourteenth Amendments to the Constitution of the United States and

1 similar protections afforded by the Washington, New Jersey, and Indiana state constitutions,
2 and that of any other state whose law is deemed to apply in this case.

3 **TWENTY-FOURTH AFFIRMATIVE DEFENSE**

4 Any claim for punitive damages against Defendants cannot be maintained because an
5 award of punitive damages under current Washington, New Jersey, and Indiana law, and any
6 other state's law deemed to apply to this action, would be void for vagueness, both facially
7 and as applied. Among other deficiencies, there is an absence of adequate notice of what
8 conduct is subject to punishment; an absence of adequate notice of what punishment may be
9 imposed; an absence of a predetermined limit, such as a maximum multiple of compensatory
10 damages or a maximum amount, on the amount of punitive damages that a jury may impose; a
11 risk that punitive damages will be imposed retrospectively based on conduct that was not
12 deemed punishable at the time the conduct occurred; and it would permit and encourage
13 arbitrary and discriminatory enforcement, all in violation of the due process clause of the Fifth
14 and Fourteenth Amendments to the United States Constitution, the due process provisions of
15 the Washington, New Jersey, and Indiana state constitutions, and the common law and public
16 policies of the states of Washington, New Jersey, and Indiana and similar protections afforded
17 by any other state whose law is deemed to apply in this case.

20 **TWENTY-FIFTH AFFIRMATIVE DEFENSE**

21 To the extent that the laws of Washington, New Jersey, and Indiana, and any other
22 state whose law is deemed to apply in this case, permit punishment to be measured by the net
23 worth or financial status of Defendants and impose greater punishment on defendants with
24 larger net worth, such an award would be unconstitutional because it permits arbitrary,
25 capricious, and fundamentally unfair punishments, allows bias and prejudice to infect verdicts
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1 imposing punishment, allows punishment to be imposed based on lawful profits and conduct
 2 of Defendants in other states, and allows dissimilar treatment of similarly situated defendants,
 3 in violation of the due process and equal protection provisions of the Fourteenth Amendment
 4 to the United States Constitution, the Commerce Clause of the United States Constitution, the
 5 state laws and constitutional provisions of Washington, New Jersey, and Indiana and similar
 6 protections afforded by any other state whose law is deemed to apply in this case.

7 **TWENTY-SIXTH AFFIRMATIVE DEFENSE**

8 Defendants are entitled to the protections and limitations afforded under Ind. Code
 9 Ann. §§ 34-51-3-1, *et seq.*

10 **TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

11 Defendants are entitled to the protections and limitations afforded under the New
 12 Jersey Product Liability Act, N.J.S.A. §§ 2A:58C-1, *et seq.* and the New Jersey Punitive
 13 Damages Act, N.J.S.A. §§ 2A:15-5.9, *et seq.*

14 **TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

15 This Court lacks personal jurisdiction over Defendant Johnson & Johnson, and
 16 therefore this Defendant must be dismissed.

17 **TWENTY-NINTH AFFIRMATIVE DEFENSE**

18 Defendants state that venue is improper.

19 **THIRTIETH AFFIRMATIVE DEFENSE**

20 Plaintiffs have failed to plead allegations of fraud, mistake, or deception with the
 21 specificity or detail required.

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THIRTY-FIRST AFFIRMATIVE DEFENSE

Defendants reserve their right to raise such further and additional defenses as may be available upon the facts to be developed in discovery and under other applicable substantive law.

Dated this 28th day of October, 2013

BENNETT BIGELOW & LEEDOM, PS

By: s/ Amy M. Magnano

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CERTIFICATE OF SERVICE

The undersigned hereby certifies under penalty of perjury under the laws of the State of Washington, that she is now, and at all times material hereto, a citizen of the United States, a resident of the State of Washington, over the age of 18 years, not a party to, nor interested in the above entitled action, and competent to be a witness herein.

I caused to be served this date the foregoing in the manner indicated to the parties listed below:

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Attorneys for Plaintiffs

Dated in Seattle, Washington this 28th day of October, 2013.

BENNETT BIGELOW & LEEDOM, P.S.

By s/ Amy M. Magnano

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